

sixty (60) days after the date this Order becomes final, one (1) year from the date this order becomes final, and annually thereafter for the next nine (9) years. The Consent Order also requires Sensormatic to notify the Commission at least thirty (30) days prior to any change in the structure of Sensormatic resulting in the emergence of a successor.

The purpose of this analysis is to facilitate public comment on the proposed Order, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way their terms.

Donal S. Clark,
Secretary.

Statement of Commissioner Mary L. Azcuenaga Concurring in Part and Dissenting in Part in Sensormatic Electronics Corp., File No. 941-0126

Today the Commission accepts for public comments a consent order that would settle allegations that Sensormatic Electronics Corporation's acquisition of Knogo Corporation's patents related to SuperStrip and the agreement to cross-license improvements to SuperStrip violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act. I find reason to believe the transaction violates the law and concur in accepting the consent order for publication. I dissent, however, from the allegations in the complaint defining the relevant market and from paragraph II(B) of the order, which requires that Sensormatic adhere to a private supply contract.

Sensormatic and Knogo produce and sell electronic article surveillance (EAS) systems and components, used by retailers to protect against shoplifting. EAS systems provide a warning when a special label attached to merchandise by the retailer triggers an electronic signal on hardware located at the store's exit unless the label has been neutralized by store employees at the time of sale. Because Sensormatic proposes to acquire only those assets of Knogo located outside North America, the competitive analysis of the transaction does not focus on the production and sale of existing EAS systems and labels to retailers in the United States and Canada.

Sensormatic, Knogo, and other firms, however, are also engaged in research and development to perfect a new "source labelling" system. In such a system, manufacturers would apply the EAS label to the merchandise or its packaging, which would eliminate the need for retailers manually to affix a label to each protected item of merchandise. No source labelling system is currently in use, but Knogo

has developed and patented SuperStrip technology for use in labels, potentially including source labels, and other firms are developing their own source labelling technologies.

I concur that the relevant market involves competition in research and development, but question the market definition in paragraph 11 of the complaint, which is narrowly limited to the research and development of "disposable labels developed or used for source labelling" and processes to make them. In a Section 7 case, the Commission has the burden of proving the relevant product market, and distinguishing research and development of source labelling from other improvements in EAS systems may be difficult or impossible. I would not limit the product market to research and development in source labelling but would define the market as research and development in EAS systems and components, including source labelling.

I also dissent from paragraph 12 of the complaint, which limits the geographic market to the United States and Canada. Successful research and development yields intellectual property that can move freely across international boundaries. A foreign firm can license intellectual property without establishing a manufacturing or sales presence in the United States. Limiting the geographic market to the United States and Canada excludes from the market the potentially important research activity of at least one European firm. Even if domestic firms are familiar with particular technologies and have a sizable base of equipment already installed in retail stores, research and development may yield an improvement significant enough to overcome the advantages of current market leaders. The market should not be so narrowly defined as to presume that only North American firms could effect a significant breakthrough that might alter the current competitive balance.

Applying Section 7 analysis to the products and geographic markets as I would define them, I find reason to believe the transaction would violate the law. The proposed acquisition would significantly increase the concentration in the already highly concentrated world market for EAS system research and development. The proposed transaction, the transfer of patents from Knogo to Sensormatic and the agreement to grant royalty-free cross licenses on any improvements to SuperStrip, likely would diminish competition in research and development of new EAS systems and

components. Accordingly, I concur in paragraph II(A) of the order.

Finally, I dissent from paragraph II(B) of the order, which provides that Sensormatic "shall comply with the terms and conditions" of a supply agreement between Sensormatic and Knogo North America, Inc., the successor corporation to Knogo's North American business. The supply agreement is a long, highly detailed commercial contract that was negotiated as part of the acquisition in question. The complaint contains no allegations establishing a relationship between this contract and the state of competition in any antitrust market. Absent a demonstrable link between the contract and competition, the contract provides no basis for liability and compliance with the contract does not appear necessary to effect relief.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94M-0414]

**Pilkington Barnes Hind USA;
Premarket Approval of Precision UV™
(Vasurfilcon A) Hydrophilic Contact
Lens for Extended Wear**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Pilkington Barnes Hind, USA, Sunnyvale, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Precision UV™ (vasurfilcon A) Hydrophilic Contact Lens for extended wear. The device is to be manufactured under an agreement with Allergan Medical Optics, Irvine, CA, which has authorized Pilkington Barnes Hind, USA to incorporate information contained in its approved premarket approval application (PMA) for the lidofilcon B nonultraviolet absorbing lens material and all related supplements that lead to the approval of the vasurfilcon A material. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 30, 1994, of the approval of the application.

DATES: Petitions for administrative review by February 27, 1995.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1744.

SUPPLEMENTARY INFORMATION: On August 12, 1994, Pilkington Barnes Hind, USA, Sunnyvale, CA 94086-5200, submitted to CDRH an application for premarket approval of the Precision UVTM (vasurfilcon A) Hydrophilic Contact Lens for extended wear. The device is a spherical soft (hydrophilic) contact lens and is indicated for nonaphakic daily or extended wear from 1 to 7 days between removals for cleaning, rinsing, and disinfecting, as recommended by the eye care practitioner. Candidates to use the Precision UVTM Hydrophilic Contact Lens include persons who are nearsighted (myopic) and farsighted (hyperopic) and who may have astigmatism of 2.0 diopters or less that does not interfere with visual acuity.

The application includes authorization from Allergan Medical Optics, Irvine, CA, 92713-9534, to incorporate information contained in its approved PMA for lidofilcon B nonabsorbing ultraviolet lens material and all related supplements that lead to the approval of the vasurfilcon A material.

In the **Federal Register** of March 4, 1994 (59 FR 10397), CDRH published an order which reclassified daily wear soft and daily wear nonhydrophilic plastic contact lenses from class III (premarket approval) into class II (special controls). CDRH notes that the daily wear indication for this lens has received marketing clearance as a class II device through the premarket notification (510(k)) procedures.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On September 30, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before February 27, 1995, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: January 11, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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Public Health Service

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Public Health Service (PHS) publishes a list of information collection requests it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following requests have been submitted to OMB since the list was last published on Friday, January 6, 1995.

(Call PHS Reports Clearance Officer on 202-690-7100 for copies of request)

1. Registration of Cosmetic Product Establishment—0910-0027 (Extension, no change)—The voluntary registration of cosmetic manufacturers and repackers supplies the Food and Drug Administration (FDA) with current locations for on-site inspections, addresses for information and regulatory mailings, business trading names supplying product distribution sources, and aids FDA in responding to FOI requests. Respondents: Business or other for-profit; Number of Respondents: 50; Number of Responses per Respondent: 1; Average Burden per Response: 0.4 hour; Estimated Annual Burden: 20 hours.

2. Progress Toward Eliminating Occupational Lead Poisoning: Survey on the Use of Lead in Industry and Control of Occupational Lead Exposure in Ohio—New—This survey will examine the types of lead-using companies doing environmental and/or biological monitoring. The results will be used to target the technical assistance resources of the National Institute of Occupational Safety and Health to those industries with uncontrolled lead exposures and those industries that should be doing monitoring and are not. Respondents: Business or other for-profit; Number of Respondents: 1,806; Number of Responses per Respondent: 1; Average Burden per Response: 3 hours; Estimated Annual Burden: 5,413 hours.

3. Small Business Innovation Research Grant Applications Phase I and Phase II and Small Business Technology Transfer Grant Applications Phase I and II—0925-0195 (Revision)—The purpose of the Small Business